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and MARK BERMAN, M.D.

14 **UNITED STATES DISTRICT COURT**
15 **CENTRAL DISTRICT OF CALIFORNIA**
16 **EASTERN DIVISION**

17 UNITED STATES OF AMERICA,
18 Plaintiff,
19 v.
20 CALIFORNIA STEM CELL
TREATMENT CENTER, INC., a
21 California corporation, CELL SURGICAL
NETWORK CORPORATION, a
22 California corporation, and ELLIOT B.
LANDER, M.D., MARK BERMAN,
23 M.D., individuals,
24 Defendants.

CASE NO. 5:18-CV-01005-JGB-KK

Hon. Jesus G. Bernal
Riverside, Courtroom 1

**DEFENDANTS' RESPONSE
TO GOVERNMENT'S
SUPPLEMENTAL
BRIEF RE: PROPER
INTERPRETATION OF
21 C.F.R. § 1271.3(D)**

Action Filed: May 9, 2018
Trial Date: May 4, 2021
Closing Arguments: August 20, 2021

1 Defendants California Stem Cell Treatment Center, Cell Surgical Network
 2 Corporation, Elliot Lander, M.D., and Mark Berman, M.D., hereby submit this
 3 response to the Government's supplemental brief regarding the proper
 4 interpretation of Section 1271.3(d).¹

5 Defendants' own supplemental brief provided a detailed and logical analysis
 6 of the plain language of Section 1271.3(d) that gives effect to *all* the words in the
 7 regulation and does not render any of them superfluous. *TRW Inc. v. Andrews*, 534
 8 U.S. 19, 31 (2001); *First Charter Financial Corp. v. United States*, 669 F.2d 1342,
 9 1350 (9th Cir. 1982). That analysis simplified the meaning of HCT/Ps under
 10 Section 1271.3(d) down to "human cells or tissues intended for implantation."
 11 That analysis also demonstrated that HCT/Ps are not defined in any way by what
 12 or how any of the cells or tissues are removed. Thus, any cells or tissues that
 13 might be removed but are *not* intended for implantation—like the adipose tissues at
 14 issue here—are not HCT/Ps for purposes of the SVF Procedure. The plain
 15 language of Section 1271.3(d) compels this straightforward conclusion.

16 And when that definition of HCT/Ps is incorporated into the SSP Exception,
 17 the exception applies when an "establishment removes HCT/Ps [or human cells or
 18 tissues intended for implantation] from an individual and implants such HCT/Ps
 19 [or human cells or tissues intended for implantation] into the same individual
 20 during the same surgical procedure." 21 C.F.R. § 1271.15. In the SVF Procedure,
 21 adipose tissues that contain SVF cells are removed from the patient, but all of the
 22 adipose tissue components are not intended for implantation and therefore are not
 23 the relevant HCT/Ps. The SVF Procedure then isolates from the removed adipose
 24 tissue the SVF cells that *are* intended for implantation, thereby making those SVF
 25 cells the relevant HCT/Ps under the SSP Exception. Those SVF cells are then
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¹ All the same defined terms and abbreviations used in Defendants' Supplemental Brief (ECF No. 178) are used herein.

1 implanted back into the same patient during the same procedure—exactly the
 2 scenario contemplated by the SSP Exception.

3 For its part, the Government notes that the definition of HCT/Ps “broad[ly]”
 4 applies to “both cells and tissues.” (Govt. Supp. Mem. at 1.) But that does not
 5 mean that *all* cells and tissues are HCT/Ps in a particular instance. Indeed, the
 6 Government elsewhere necessarily acknowledges that HCT/Ps are limited to only
 7 those cells or tissues “intended for implantation” (Govt. Supp. Mem. at 2), which
 8 renders the conclusion of which cells or tissues are HCT/Ps in a particular instance
 9 dependent on what is “intended for implantation.”

10 Despite this acknowledgment, the Government quickly loses sight of that
 11 limitation and improperly focuses on what is removed when it argues that, “if an
 12 article containing cells intended for implantation is removed, ‘such’ article
 13 containing cells must be reimplanted.” (*Id.*) An “article *containing* cells” would
 14 no doubt refer to the tissues surrounding the cells—like the adipose tissues at issue
 15 here—because it *is* a technological impossibility to remove only cells. (*See* 5/7/21
 16 PM Tr. 19:9-12 (Yong); 5/11/21 AM Tr. 112:13-19 (Berman)).² But that
 17 interpretation renders the inclusion of “cells” superfluous because there would
 18 never be an article *consisting of* cells removed, as Section 1271.3(d) plainly
 19 contemplates.

20 The Government essentially concedes this reality when it fails to give
 21 meaning to the inclusion of “cells” and claims “it is no fault of the regulation” that
 22

23 ² The Government’s argument that it “*is possible*” to remove cells, e.g., an
 24 ovocyte/oocyte, without removing other parts is rightly relegated to a footnote.
 25 (Govt. Supp. Memo. at 3, n.3.) This lone example regarding female germ cells that
 26 are the precursor to human eggs/embryos hardly demonstrates how HCT/Ps are
 27 defined for purposes of the SSP Exception, as no surgical procedure exists where
 28 the *same* ovocyte/oocyte removed from a patient is implanted back into the same
 patient unchanged—it would always be mixed with semen or sperm cells to
 become a fertilized egg or embryo before implantation. Moreover, any other type
 of cells that could potentially be isolated for removal would need to be transmitted
 back into a person utilizing a transportation vehicle, e.g., saline, prior to re-
 implantation to keep the cells viable.

1 cells cannot be removed. (Govt. Supp. Mem. at 3.) Moreover, this punt as to the
 2 plain language of Section 1271.3(d) fails to abide by settled canons of construction
 3 requiring that any proper regulatory interpretation gives meaning to all the words
 4 and does not render any of them superfluous. *TRW*, 534 U.S. at 31; *First Charter*,
 5 669 F.2d at 1350. But the focus on what is “intended for implantation” does not
 6 “creat[e] a brand new regulatory exception,” as the Government claims (*id.*);
 7 it interprets HCT/Ps exactly as the plain language of Section 1271.3(d) dictates.
 8 The fact “many establishments” already “can and do remove HCT/Ps and implant
 9 such HCT/Ps in compliance with the SSPE” (*id.*) does not mean the plain language
 10 of Section 1271.3(d) and the SSP Exception does not apply to the SVF Procedure.
 11 It does.

12 The Government feigns a parade of horribles when it claims “the proposed
 13 interpretation” that gives effect to *all* the words in Section 1271.3(d) would mean
 14 that “nearly all autologous HCT/Ps may qualify for the narrow SSPE,” thereby
 15 “result[ing] in untold harm to patients.” (*Id.*) Despite its hyperbole, the scenario
 16 the Government proffers—where cells or tissues intended for implantation are
 17 removed from a patient, those cells or tissues are minimally processed and remain
 18 unchanged, and then are re-implanted into the same patient during the same
 19 procedure—is exactly what the SSP Exception contemplates. The Government’s
 20 bald claim of “untold harm to patients” is unsubstantiated and irrelevant to the
 21 issue of statutory interpretation.

22 Finally, the Government uses half its submission to extend beyond the
 23 limited statutory/regulatory interpretation issues on which the Court invited
 24 briefing and instead re-argues the merits. Defendants will limit their response to
 25 make two discrete points. First, the Government is patently wrong when it claims
 26 that it was “established at trial” that “SVF is not naturally occurring.” (Govt.
 27 Supp. Mem. at 4.) Even the Government’s witness testified that SVF cells *are* the
 28 naturally occurring part of the adipose tissue that does not contain the adipocytes

1 (fat cells). (5/7/21 PM Tr. 28:18-31:8 (Yong) (“Q. And adipose-derived stem cells
 2 are naturally found within adipose tissue; correct? A. To my knowledge, yes.”);
 3 *see also* 5/11/21 AM Tr. 112:20-24 (Berman); 5/12/21 PM Tr. 47:4-6 (Lander)).
 4 Second, the Government’s invocation of “public health protections” (Govt. Supp.
 5 Mem. at 4) is specious where, as here, Defendants have offered the SVF Procedure
 6 to patients for more than *ten* years (5/11/21 PM Tr. 46:8-11 (Berman)) to aid in
 7 their healing by allowing an increased quantity of the optimal healing SVF cells to
 8 be added to specific areas (e.g. joints) or the general circulation. During that same
 9 time, the FDA has declined to test a single SVF cell, despite the ability to do so.
 10 (5/6/21 AM Tr. 67:13-15; 67:25-68:2 (Lapteva); 5/7/21 PM Tr. 21:11-13; 22:3-16
 11 (Yong); (5/12/21 PM Tr. 90:2-7 (Lander)). The SVF Procedure is a surgical
 12 procedure that resides well within the discretion of physician-patient discussions
 13 and decisions, like most surgeries, and implicates fundamental rights of patient
 14 privacy and bodily autonomy. *See Roe v. Wade*, 410 U.S. 113 (1973); *Griswold v.*
 15 *Connecticut*, 381 U.S. 479, 485 (1965). Thus, applying the SSP Exception to the
 16 SVF Procedure fully comports with the public health protections our laws should
 17 advance.

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Respectfully submitted,

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JONES DAY

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